DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 10, 2015

CoreLeader Biotech Company, Ltd.
Dr. Ya-Wen Kuo
Manager, Regulatory Affairs
19F, Building B, Number 100, Section 1,
Xintai 5th Road, Xizhi District
New Taipei City 22102
Taiwan

Re: K141382
Trade/Device Name: Bios King Biocellulose Film
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 14, 2015
Received: January 16, 2015

Dear Dr. Kuo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K141382

Device Name: Bios King Biocellulose Film

Indications for Use:

Bios King Biocellulose Film is indicated as a topical dressing to manage pressure sores, diabetic ulcers, 1st to 2nd degree burns and skin donor sites.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitted by:	CoreLeader Biotech Co., Ltd. 19F, No. 100, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan, R.O.C. 22102 Phone: +886-2-26968880 FAX: +886-2-26968882
Contact Person:	Ya-Wen Kuo
Date Prepared:	2014/04/19
Proprietary Name:	Bios King Biocellulose Film
Common Name:	Topical wound dressing
Classification:	Unclassified
Classification Name:	Dressing, Wound, Drug
Predicate Device:	1. BioFill Biocellulose Dressing Sterile (The Purdue Frederick Co.): K950621 2. X-CELL Wound Dressing (Xylos Corporation): K974251

Device Description:

Bios King Biocellulose Film is made of bacterial synthesized cellulose mesh with a selectively permeable structure allowing water evaporation, and thus provides a moist but not damp environment for wound healing. Bios King Biocellulose Film is resistible to the tensile force generated from the wound handing. It can adhere to wound beds without fixation devices.

Indications for Use:

Bios King Biocellulose Film is indicated as a topical dressing to manage pressure sores, diabetic ulcers, 1st to 2nd degree burns and skin donor sites.

Technological Characteristics:

Bios King Biocellulose Film is made of biocellulose mesh synthesized by a gram-negative bacteria strain called acetobacter xylinum, which secrets a large quantity of organized and twisted cellulose microfibrils. The pores within the Bios King Biocellulose Film permit water vapor transportation. Bios King Biocellulose Film is removed of water content through lyophilization process. After that, it barely absorbs water. Bios King Biocellulose Film passes endotoxin test, cytotoxicity test, skin irritation test and maximized skin sensitivity test following ISO 10993 protocols. Bios King Biocellulose Film biocellulose film encompasses tensile strength and readily conforms to irregular wound shapes.

Substantial equivalence:

The safety and efficacy of Bios King Biocellulose Film are substantially equivalent to the predicate devices, including BioFill Biocellulose Dressing Sterile (K950621) and X-CELL Wound

Dressing (K974251) in the aspect of indications for use, materials, mode of action, sterility, biocompatibility, water vapor transmission, and directions to use.

1 Indications for use: Similar to the predicate devices, Bios King Biocellulose Film is intended to be used as a topical dressing to manage pressure sores, diabetic ulcers, 1st to 2nd degree burns and skin donor sites.

2 Mode of action: Similar to the predicate devices, the selectivity of substance transportation though Bios King Biocellulose Film is determined by the fine pores within the film constructed by layers of biocellulose micro fibrils. The pores are small that they allow the entry of water vapor.

3 Materials: Similar to the predicate devices, Bios King Biocellulose Film is made of biocellulose micro fibrils synthesized by a gram-negative bacteria strain called acetobacter xylinum. Biocellulose film is fabricated through a week of exclusive fermentation process and removed of endotoxcity origins through alkine treatment. The water within the biocellulose film is removed though lyophilization process.

4 Non-clinical tests

4.1 Sterility: Similar to the predicate devices, Bios King Biocellulose Film is sterilized to 10^{-6} SAL using gamma ray. The sterilization validation tests meet the criteria of ISO 11137-1, -2: 2006: Sterilization of health care product radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices; Part 2: Establishing the sterilization dose.

4.2 Shelf life: The shelf life of Bios King Biocellulose Film is 5 years when the product is stored at room temperature without sun light exposure. The shelf life is determined through the stability test using accelerated aging model.

4.3 Biocompatibility: Bios King Biocellulose Film is as biocompatible as the predicate devices.

4.3.1 Endotoxin Test: The endotoxin level of Bios King Biocellulose Film is lower than 20 EU/device.

4.3.2 Cytotoxicity: Bios King Biocellulose Film passes *in vitro* cytotoxicity test required in ISO 10993-5.

4.3.3 Intracutaneous reactivity: Bios King Biocellulose Film passes the intracutaneous reactivity test required in ISO 10993-10.

4.3.4 Skin sensitization: Bios King Biocellulose Film passes skin sensitization test required in ISO 10993-10.

4.3.5 Heavy metal test: CoreLeader Bios King is free of heavy metal contamination, including arsentic, cadmium, copper, lead, and mercury.

5 Performance:

5.1 Moisture vapor transmission rate: Bios King Biocellulose Film is water vapor permeable. The moisture vapor transmission rate is greater than 800 g/m^2 x 24hr. The test follows protocols of ASTM E96-95: Standard Test Method for Water Vapor Transmission of Materials and EN 13726-2 (2002): Test methods for primary wound dressings–Part 2: Moisture vapor transmission rate of permeable film dressings

5.2 Mechanical strength: The tensile strength of Bios King Biocellulose Film larger than 1000 g/25mm.

The results and references of non-clinical tests of Bios King Biocellulose Film are listed in Table 1. According to the results of the aforementioned non-clinical tests, the substantial equivalences of Bios King Biocellulose Film to the predicate devices are summarized in Table 2

Table 1. The list of non-clinical tests conducted to validate the safety and efficacy of Bios King Biocellulose Film to achieve the indications as claimed.

Test	Conclusion	Guidance
Sterilization validation test	Bios King Biocellulose Film is sterile to 10^{-6} SAL after 25kGy gamma radiation.	ISO 11137-1, -2: 2006
Shelf life test report	Bios King Biocellulose Film is expired 5 years after manufacturing.	ASTM F1980-02
Endotoxin test	Bios King Biocellulose Film will not cause endotoxin hazard as a skin wound dressing.	USP <85> USP <161>
Cytotoxicity test	Bios King Biocellulose Film will not cause cytotoxicity hazard as a skin wound dressing.	ISO 10993-5:1999
Intracutaneous reactivity test	Bios King Biocellulose Film will not cause skin irritation hazard as a skin wound dressing.	ISO 10993-10: 2002. ISO 10993-12:2012.
Skin sensitization test	Bios King Biocellulose Film will not cause skin sensitization hazard as a skin wound dressing.	ISO 10993-10: 2010. ISO 10993-12:2012.
Heavy metal residue test	The arsenic, cadmium, copper, mercury are undetectable. The lead is lower than 5 ppm	ICP-AES analysis
Moisture vapor transmission test	Moisture vapor rate is over 800 g/m^2 x 24 hr	EN 13726-2 (2002) ASTM E96-95
Tensile strength	Bios King Biocellulose Film is tensile resistant with tensile strength larger than 1000 g/25 mm.	Internal protocol of Taiwan Textile Research Institute

Table 2. Substantial equivalence comparison with the predicate devices.

	Proposed device	Predicate device	
	CoreLeader Bios King Biocellulose	X-CELL Wound Dressing	BIOFILL Biocellulose Dressing Sterile

Indications	Bios King Biocellulose Film is intended to be used as a topical dressing to manage pressure sores, diabetic ulcers, 1st to 2nd degree burns and skin donor sites.	X-CELL Wound Dressing is intended to cover a wound or burn on a patient's skin to absorb wound exudates, and protect against abrasion, friction, or external contamination.	Chronic wounds
Ingredient	Bacterial cellulose	Bacterial cellulose	Bacterial cellulose
Mode of action	Substance transportation though Bios King Biocellulose Film is determined by the pore size of cellulose dressing.	Substance transportation is determined by internal pore size of dressing.	Substance transportation is determined by internal pore size of dressing.
Sterilization	25kGy gamma radiation to reach 10^{-6} SAL	Sterile	Sterile
Shelf life	5 years	3 years	3 years
Endotoxin test	Lower than 20 EU/device	pass	pass
In vitro cytotoxicity test	No cytotoxicity	No cytotoxicity	No cytotoxicity
In vivo rabbit skin irritation test	No skin irritation	No skin irritation	No skin irritation
In vivo guinea pig skin sensitization test	No skin sensitization	No skin sensitization	No skin sensitization
Heavy metal test	No heavy metal contamination	No heavy metal contamination	No heavy metal contamination
Moisture vapor transmission test	Moisture vapor transmissible	Yes	Yes